

### **REMARKS**

Claims 12 and 16-18 have been amended to reinstate the language deleted in the paper filed July 9, 2003 and conform to the claims stated as distinct from the interference count. Claims 95 (second occurrence) and 96 have been renumbered to correct them. No new matter has been added by virtue of these amendments and new claims. Their entry is respectfully requested.

applicants confirm that Claim 41 was not cancelled and is pending.

Applicants appreciate the acknowledgement of patentable subject matter at least in claims 21 and 75.

Claims 50 through 68 previously were added from co-pending application Ser. No. 08/903,830 (corresponding to claims 13 through to 30, and 33), now abandoned. These claims of U.S. Ser. No. 08/903,830 were allowed in a Notice of Allowance dated May 21, 2003. U.S. Ser. No. 08/903,830 has the same specification as the present application.

Claims 68 through 97 previously were added from co-pending application No. 09/034,464 (corresponding to claims 1 through 8 and 15 through to 35), now abandoned. U.S. Ser. No. 08/903,830 has the same specification as the present application.

Regarding Interference No. 104,363, in the decision on motions mailed May 18, 2001 setting forth the basis for redeclaration of the interference, the Board stated that Knipe claims 12-22, 31, 36 and 41 do not correspond to Count 2. The Board further stated, at page 49,

In effect, Count 2 provides Knipe with the relief sought insofar as it omits Knipe claims 1, 5, 12, 17 and 18 from Count 2.

However, although claims 1 and 5 were found to not correspond to Count 2, based on the record in interference, claims 1 and 5 were found unpatentable because of an error in establishing Knipe's priority claim, which made Knipe's own publication prior art during the interference, even though it is not prior art.

Claim 1 stated as follows:

1. A pharmaceutical composition comprising a mutated herpesvirus in a pharmaceutically acceptable carrier, the herpesvirus having a mutation in one or more genes encoding a protein essential for viral genome replication to render the herpesvirus replication defective, said mutant herpesvirus having an ability to effect an antibody subclass shift of IgG2a/IgG upon *in vivo* administration to a mammal.

Claim 5 stated as follows:

5. A pharmaceutical composition comprising a mutated herpesvirus in a pharmaceutically acceptable carrier, the herpesvirus having a mutation in one or more genes encoding a protein essential for viral genome replication to render the herpesvirus replication defective, said mutant herpesvirus having an ability to induce production of IFN- $\gamma$  upon administration to a mammal.

Because Knipe is entitled to the benefit of the parent application Ser. No. 07/922,912 filed July 31, 1992, the Knipe publication is not prior art in this examination proceeding.

Claims 50-70, 73, 74 and 76 -96 [sic, 97] are rejected under 35 U.S.C §112, first paragraph. The Examiner states that this application has no disclosure of the "UL5" subject matter now claimed. The Examiner also requests Applicant to point to support for the nonsense and deletion mutations recited in new claims 53, 60, 65, 67, 76, 87, 90, 93 and 95, and the "B-cell and/or T-cell response" in new claim 96 [sic, 97].

Applicant agrees that the present application has no specific disclosure of the "UL5" subject matter. This has been deleted in the above amendment.

Support for the new claims is found throughout the application. For example, construction of mutants is described on 7, lines 2 to 35; and page 16, lines 4 to 34 through to page 20, lines 1 to 35. Types of mutations, e.g. nonsense, deletion etc, are described on page 8, lines 1 through 16 and figures 4 and 5; Preferred double mutations are described on page 8, lines 17 to 21 and on page 10, lines 10-15; specific mutations are described on page 8, lines 22-28; characterization of mutants is described on page 21 lines 1 to 21 through to page 29, lines 1 to 26. B and T cell responses to the mutants are described on page 40, line 1 through page 51 line 9.

The specific combination of a nonsense mutation in ICP27 and a deletion mutation in ICP8 is apparent to one skilled in the art from the disclosure on page 8, lines 7-28, where it is taught that preferred embodiments contain one or more mutations in the ICP8 and/or ICP27 genes and certain preferred embodiments include a nonsense mutation of ICP27 (i.e., n504R) and a deletion mutation of ICP8 (e.g., d27, d301). Therefore, one skilled in the art would know that Applicants were in possession of the invention of claims 53, 60, 65, 67, 76, 87, 90, 93 and 95 at the time of filing the application.

Claims 31 and 36 are rejected under 35 U.S.C §112, second paragraph. Applicant intended to claim a composition that elicits an immune response in view of the

examiner's comments in the paper dated February 12, 2003. applicant has amended the claims accordingly in view of the present comments of the Examiner.

Claims 16-20 are rejected under 35 U.S.C §112, first paragraph. The above amendment renders this matter moot.

Claims 12-15 are rejected under 35 U.S.C. §102(g) or, in the alternative, 103 U.S.C. §103(a). The above amendment renders this rejection moot.

Claims 50-64 and 66 are rejected under 35 U.S.C. §102(g), in the alternative, 103 U.S.C. §103(a). The presently claimed invention is directed to compositions including a herpesvirus have two or more deletions rendering the herpesvirus incapable of replication. It is respectfully submitted that this subject matter would not have been obvious to one of ordinary skill in the art in view of the interference count.

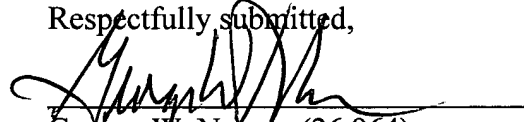
Claims 36 and 41 are rejected under 35 U.S.C. §102(b) over Dobson et al (Neuron 5:353-60, 1990). Dobson describes a genetically engineered herpes simplex virus having a deletion in the early intermediate gene ICP4, which inhibits replication. There is no teaching or suggestion for a "herpesvirus comprising a mutation in one or more early genes encoding a protein essential for viral genome replication to render the herpesvirus replication defective." It is respectfully submitted that "a deletion in the early intermediate gene ICP4, which inhibits replication" is not a teaching or suggestion for "a mutation in one or more early genes encoding a protein essential for viral genome replication to render the herpesvirus replication defective."

Thus, it is not seen how the present invention is anticipated by, or would have been obvious to one of ordinary skill in the art in view of, Dobson.

Applicant: KNIPE et al.  
Serial No.: 08/278,601  
Page 17 of 17

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested. If any issues remain, the Examiner is requested to call Applicants' undersigned attorney to expedite the resolution of such issues.

Respectfully submitted,

  
George W. Neuner (26,964)

Date: June 30, 2004

EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, Massachusetts 02205

Tel. (617) 439-4444  
Fax (617) 439-4170  
Direct Dial 617-517-5538

Customer No. 21874

BOS2\_449908.1